

Section II. (REMARKS)**Determination of Non-Responsiveness of the August 2, 2004 Amendment to the March 2, 2004 Office Action, and Amendment of Claims Herein as Obviating Such Determination**

In the October 18, 2004 Official Communication, the August 2, 2004 Amendment filed in this application was determined to be non-responsive to the March 2, 2004 Office Action.

The Examiner based her determination on the following reasons stated in the October 18, 2004

Official Communication:

"The Amendment filed August 2, 2004 canceling all claims drawn to the elected invention, i.e., methods of combating movement disorder in a patient experiencing or susceptible to same, by administering a neurotransmission modulating composition comprising a 5HT antagonist and/or alpha-2 antagonist" ...

"The new claims are not readable on the elected invention because they are directed to methods of combating movement disorder in a patient experiencing or susceptible to such movement during treatment with a dopaminergic medication, an anticonvulsant medication or an antianxiolytic medication comprising administering mirtazapine, as well as compositions comprising (i) a dopaminergic medication, an anticonvulsant medication or an antianxiolytic medication and (ii) mirtazapine."

The determination of non-responsiveness of the Amendment therefore rests solely on the presence of the single composition claim 45 in the claims of the August 2, 2004 Amendment, since the limitation of "during treatment with a dopaminergic medication, an anticonvulsant medication or an antianxiolytic medication" in the other claims (in claim 31, from which all other claims 32-44 were directly or indirectly dependent) merely further characterized the patient in the claimed methodology, and did not change the status of the corresponding method claims in respect of the election.

BEST AVAILABLE COPY

In fact, the only election requirement of record in the present application is the election of species requirement imposed by prior Examiner William Jarvis in the January 15, 2003 Office Action, wherein that Examiner stated that

“Applicant is required under 35 U.S.C. 121 to elect a single disclosed species from each class (i.e., a 5-HT antagonist and/or an α -2 antagonist or one compound exhibiting both activities).”

In a Response filed February 18, 2003, the election was made as follows:

“In response, applicant elects ‘one compound exhibiting both activities’ and elects mirtazapine as a single disclosed compound, viz., 1,2,3,4,10,14b-hexahydro-2-methyl-pyrazino [2,1-a]pyrido [2,3-c]benzazepine).”

This response was acknowledged by the present Examiner in the July 1, 2003 Office Action.

Since applicants have in the present Amendment canceled claims 15-30, and amended method claims 1-7 and 9-14 (method claim 8 remaining in original form) to be limited to mirtazapine, there is no infirmity of elected subject matter in the claims 1-14 now pending in the application.

Amendment of Claims 1-7 and 9-14 and Patentable Character of Claims 1-14

All of the now-pending claims 1-14 are directed to the elected species, mirtazapine, which the examiner has indicated “to be free of the prior art” (page 2, lines 2-3 of the March 2, 2004 Office Action).

No new matter (35 USC 132) has been added.

Claim 1 has been amended to recite a method of combating movement disorder in a patient experiencing or susceptible to same who is being treated with dopaminergic medication, anticonvulsant medication or antianxiolytic medication, said method comprising administering to the patient an effective amount of mirtazapine. Such claim is consistent with Examples 1-6. As mentioned, method claim 1 fully comports with the election requirement of record, and applicants’ response thereto, of record. Claim 1 therefore has no infirmity as to its subject matter.

Concerning the dependent claims 2-14 under claim 1, the same are likewise fully consistent with and supported by the as-filed disclosure of the application.

The dopaminergic medication (claim 2) can include a dopa agonist (claim 3; Examples 2 and 3), with specific dopaminergic medication ingredients (claim 4) including levodopa (Example 6), levodopa in combination with carbidopa (Sinemet; Examples 1-3), or ropirinoles (Example 2).

The anticonvulsant medication (claim 5) can include primidone (Mysoline; Example 4) (claim 10).

The antianxiolytic medication (claim 11) can include (Example 5) propranolol (claim 12), an SSRI (claim 13) or a benzodiazepine (claim 14).

The movement disorder can include bradykinesia (claim 6; Examples 1-3), tremor (claim 8; Examples 2-6), resting tremor (claim 7; Examples 2, 3 and 6), and action tremor (claim 9, Examples 4 and 5).

All pending claims 1-14 therefore embody the elected species.

Rejection of Claims on Reference Grounds under 35 CFR §102(b) and 35 USC §103(a)

In the March 2, 2004 Office Action, the previously pending elected claims 1-14, 16, and 18-30 were rejected on various grounds, including:

- a rejection of claims 1-14, 16, 18, 23, 24, 26-28 and 30 "under judicially created doctrine as being drawn to an improper Markush group;"

- a rejection of claims 1-14 and 18, 23, 24, 26-28 and 30 under 35 USC 112, first paragraph as non-compliant with the written description requirement;

- a rejection of claims 3 and 16 under 35 USC 112, second paragraph as failing to particularly point out and distinctly claim the invention;

- a rejection of claims 1-4, 6-12, 13, 26, 27 and 30 under 35 USC 102(b) as anticipated by Henry et al., Experimental Neurology; and

- a rejection of claims 1-5, 6-14, 16, 18, 23-28 and 30 under 35 USC 102(b) as anticipated by Lin-Shiau et al., Pharmacol., Biochem. Behav.


These various rejections now are moot in view of the amendment herein of claims 1-7 and 9-14.

All pending claims 1-14 are now directed to the elected species, mirtazapine, which has been characterized by the examiner "to be free of the prior art" (page 2 of the March 2, 2004 Office Action).

Further, the pending claims 1-14, as discussed in preceding remarks, are based on and directly supported by the specific examples in the application. All claims 1-14 are now of proper form and fully in compliance with the requirements of 35 USC 112. No improper Markush group is present in any claim.

Accordingly, all claims 1-14 now pending in the application are patentable over the art and in condition for allowance. Favorable action therefore is requested.

Respectfully submitted,



Steven J. Hultquist
Reg. No. 28,021
Attorney for Applicants

INTELLECTUAL PROPERTY/
TECHNOLOGY LAW
Phone: (919) 419-9350
Fax: (919) 419-9354
Attorney File No.: 4164-101 CON

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ **BLACK BORDERS**
- ☐ **IMAGE CUT OFF AT TOP, BOTTOM OR SIDES**
- ☐ **FADED TEXT OR DRAWING**
- ☐ **BLURRED OR ILLEGIBLE TEXT OR DRAWING**
- ☐ **SKEWED/SLANTED IMAGES**
- ☐ **COLOR OR BLACK AND WHITE PHOTOGRAPHS**
- ☐ **GRAY SCALE DOCUMENTS**
- ☐ **LINES OR MARKS ON ORIGINAL DOCUMENT**
- ☐ **REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY**
- ☐ **OTHER:** _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.